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PT. SINKO PRIMA ALLOY

Alamat : Jl. Tambak Osowilangun Permai No. 61,
pergudangan osowilangun permai Blok
E7-E8, Surabaya-Indonesia (60191)

Telepon : 031-7482816

Fax. : 031-7482815

Aftersale (WA) : 0821-4281-7085

Email : aftersales@elitech.co.id
sinkoprima@gmail.com

Website : www.elitech.id

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Contents

Chapter 1	Safety.....	2
1.1	Instructions for Safe Operations	2
1.2	Warning	2
1.3	Attention.....	2
Chapter 2	Overview	3
2.1	Brief Introduction	3
2.2	Features	3
2.3	Accessories	3
2.4	Environment Requirements	3
Chapter 3	Operating Principle of Oximeter.....	4
Chapter 4	Technical Specifications	5
4.1	Main Functions	5
4.2	Main Parameters	5
Chapter 5	Operating Guide	6
5.1	Connection	6
5.1.1	Sockets	6
5.1.2	Power Supply	6
5.2	Start and Close.....	7
5.3	Functions	7
5.3.1	Simulations.....	8
5.3.2	Alarm Limits	10
5.3.3	Amplitude.....	12
5.3.4	Preset	13
5.3.5	Setting	14
5.3.6	R-Curve.....	17
Chapter 6	Maintain, Transportation and Storage.....	18
6.1	Maintain	18
6.2	Transportation and Storage	18
Chapter 7	Troubleshooting.....	19
Chapter 8	Key of Symbols.....	20
Chapter 9	Function Specification	21

Chapter 1 Safety

1.1 Instructions for Safe Operations

- ✧ Check periodically to make sure that there is no visible damage that may affect device's test performance. It is recommended that the device should be inspected weekly at least. When there is obvious damage, stop using the device.
- ✧ Necessary maintenance must be performed by qualified service engineers ONLY. Users are not permitted to maintain it by themselves.
- ✧ Only the accessory that is appointed or recommendatory by manufacture can be used with this device.
- ✧ This product is calibrated before leaving factory.

1.2 Warning

- ⚠ Explosive hazard—DO NOT use the device in the environment with tinder such as anesthetic.
- ⚠ The disposal of scrap instrument and its accessories and packing (including plastic bags, foams and paper boxes) should follow the local laws and regulations.
- ⚠ Please check the packing before use to make sure the device and accessories are totally in accordance with the packing list, or else the device may have the possibility of working abnormally.
- ⚠ Please choose the accessories which are approved or recommended by the manufacturer, or else it may damage the device.

1.3 Attention

- ⚠ Keep the simulator away from dust, vibration, corrosive substances, tinder, too high or low temperature and moisture.
- ⚠ If the device gets wet, please stop operating it.
- ⚠ When it is carried from cold environment to warm or humid environment, please do not use it immediately.
- ⚠ DO NOT operate keys on front panel with sharp materials.
- ⚠ DO NOT have the device immersed in liquid. When it needs cleaning, please wipe its surface with medical alcohol by soft material. Do not spray any liquid on the device directly.

Chapter 2 Overview

2.1 Brief Introduction

SpO₂ Simulator is a kind of Separated SpO₂ simulator, small and light. It can perform a series of tests for the oximeter by simulation means, and give cognizance of veracity about the oximeter.

As different manufactures may use different R-curve, the stimulator is embedded parts of current popular R-curve in advance.

2.2 Features

- 1) Separated connection between simulator probe and host, makes operation and test more convenient.
- 2) 262K color and 320*240 TFT, adjustable brightness level.
- 3) Film key-press, makes the operation more comfortable.
- 4) Power with rechargeable lithium battery, can display the charge information of battery.
- 5) Key volume, can open or close.

2.3 Accessories

- 1) user manual (1)
- 2) 5.0V adaptor (1)
- 3) SpO₂ Simulator Probe(1)

2.4 Environment Requirements

Storage Environment

- a) Temperature: -20°C~+65°C
- b) Relative humidity: <90%
- c) Height above sea level: 3000m

Operating Environment

- a) Temperature: 15°C~40°C
- b) Relative Humidity: <90%
- c) Height above sea level: 3000m
- d) Power supply: DC 3.7V~4.2V, rechargeable lithium battery.

Chapter 3 Operating Principle of Oximeter

Pulse oximeter is a device which measures the rate of two important hemoglobins(saturated arterial hemoglobin(HbO_2/SAT), Reductive Hemoglobin (Hb)) in blood. Arterial oxygen saturation is defined as the ratio of cHbO_2 (the concentration of HbO_2) and $\text{cHbO}_2 + \text{cHb}$ (the concentration of Hb). SpO_2 shows with the type of percentage, and calculates as follows:

$$\text{SaO}_2 = \frac{\text{cHbO}_2}{\text{cHbO}_2 + \text{cHb}} * 100\%$$

With above information, a calibrated oximeter can measure accurately the level of the oxygen in blood, which can provide some valuable data for the patient's healthy state and the state of the patient who is recovering from anaesthesia and operation.

Chapter 4 Technical Specifications

4.1 Main Functions

- 1) Oxygen saturation simulation;
- 2) Pulse rate simulation;
- 3) Presetable patient state simulation;
- 4) Reaction time of the tested device can be tested;
- 5) Stimulate the SpO₂ and pulse rate under different amplitudes;
- 6) Test the performance under different interference source;
- 7) Selectable different R-curve.

4.2 Main Parameters

1) SpO₂

Range: 35%~100%

Resolution: 1%

Accuracy: When SpO₂ is 75%~100%, the error is $\pm 2\%$ or the device's accuracy, whichever is greater; when SpO₂ is 74%~50%, the error is $\pm 3\%$ or the device's accuracy, whichever is greater; no definition when SpO₂ is less than 50%.

2) Pulse rate

Range: 25bpm~250bpm

Resolution: 5bpm

Accuracy: $2\% \pm 2\text{bpm}$

3) Measurement Performance in Amplitude

Range: 0.000%~20.000%

Resolution: 1% for 1.000%~20.000%; 0.1% for 0.100%~0.900%; 0.025% for 0.000%~0.075%.

4) Patient state

24 conditions presetting and 8 conditions as default state, adjust the number of patient state by setting motion level.

5) Working voltage

DC 3.7V~4.2V

6) Working current

Working current: $\leq 500\text{mA}$

7) Battery

3.7V rechargeable lithium battery

Chapter 5 Operating Guide

5.1 Connection

5.1.1 Sockets



Figure 5-1 Sockets Sketch

Adapter jack locates on the right panel, which is used for connecting adapter for charging internal lithium battery. The socket for simulator probe locates on the left panel, when it connects properly, the device can measure.

- ⚠ Pull in/out the simulator probe according to the direction of the arrowhead on the plastic connector plug.
- ⚠ Please keep the gleamy surface of the tested device on the same side with silk-screen side of simulator probe, adjust the position of the tested device to get the exacter value.
- ⚠ Only the simulator probe from our company can be used to connect, otherwise it may cause some danger or damage to the device.



Figure 5-2 Connect Sketch for Simulator probe



Figure 5-3 Silk-screen Sketch for Simulator probe

5.1.2 Power Supply

Built-in lithium battery (4000mAh/3.7V), when low-battery appears, please use the adapter provided by our company to charge, it is not recommended to use the device during charging.

- ⚠ The indicator on the top right is red when it is charging, green indicates finish charging.
- ⚠ Built-in battery, don't change it by yourself.
- ⚠ For the device not used for long, please cut off the equivalent power, and charge it once a month.

5.2 Start and Close


Long-press the power button , until hearing a prompt sound of start. First system will enter the welcome interface, then prompt the current R-Curve, and enter the Main Menu lastly. shown as Figure 5-4:



Figure 5-4 Main Menu

The menus in turn are: Simulation, Alarm Limits, Amplitude (viz. perfusion degree), Preset, setting, R-Curve. Select the corresponding menu with UP, DOWN, LEFT, RIGHT keys and enter corresponding interface by pressing OK key.

Long-press Power key in any interface, it will display "Bye bye!" and close.

 You can identify the selected menu by a blue rectangle frame.

5.3 Functions

It will check the red LED and infra-red LED normal or not when entering or exiting Simulation and Alarm Limits menu. If normal, the operation is responded immediately; or else, a prompt "NO RED LED NO IRED LED Check probe or press Back".

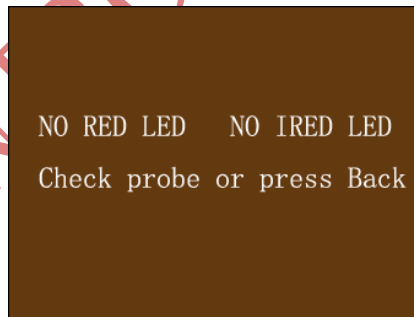


Figure 5-5 Check Prompt

5.3.1 Simulations



Figure 5-6 Simulations

The tests in this interface are:

- 1) Manual
- 2) Ambient Light
- 3) TLC
- 4) Auto Test

Press UP and DOWN to select the item, press OK key to enter, and press Back to exit to the superior menu. No operation for LEFT and RIGHT.

① Manual



Figure 5-7 Manual

In this interface, SpO₂ and Rate can be adjusted manually. Press the LEFT and RIGHT key to set the adjusting item, and press Back key to return the menu of last level. No operation for OK key.

a. SpO₂ setup

Move the prompt symbol to "SpO₂", and press UP and DOWN to increase and decrease the SpO₂ value with the step size. Default value after start is 96%.

b. Rate setup

Move the prompt symbol to "Rate", and press UP and DOWN to increase and decrease the Rate value with the set step size. Default value after start is 75bpm.

About step size setup, please refer to the content of 5.3.5.

② Ambient light simulation

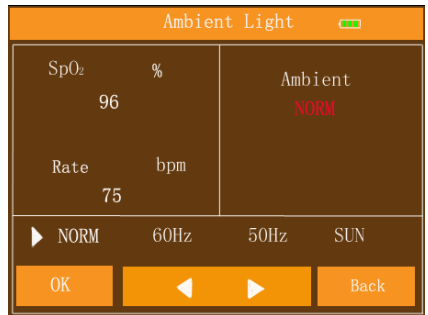


Figure 5-8 Ambient Light

In this interface, the tests in the interference state are as follows:

- a. NORM (normal state)
- b. 60Hz AC interference
- c. 50Hz AC interference
- d. SUN

Press LEFT and RIGHT to adjust the item where the prompt symbol is, and press OK key to confirm the setting. Press Back to exit to the superior menu. No operation for UP and DOWN.

③ TLC



Figure 5-9 TLC

The display information in this interface includes:

- 1) Trans Level Ctrl(0000~4095)
- 2) Step Size(5~100)
- 3) Default

Press UP and DOWN to adjust the corresponding item, press Back to return to the superior menu. OK is usable only in the Default item.

- a. Trans Level Ctrl setup

Move the prompt symbol to "Trans Level Ctrl", and press LEFT and RIGHT to increase and decrease its value with the step size.

b. Step size setup

Move the prompt symbol to "Step size", and press LEFT and RIGHT to increase and decrease its value.

c. Default

Move the prompt symbol to "Default", and press OK to recover the simulation level to the default value.

The default values of the simulation level are different according to the different R-curves.

④ Auto Test



Auto test mode testing for SpO2, Rate, Amplitude parameters, and testing with interference.

5.3.2 Alarm Limits



Figure 5-10 Alarm Limits

This interface is used to test the reaction time of oximeter. The testing items here are:

- a. SpO₂
 - b. Rate
 - c. Asystole
- 1) SpO₂ Alarm

Press UP and DOWN to move the prompt symbol to "SpO₂ Alarm", press OK to enter the interface as follows:



Figure 5-11 SpO₂ Alarm

Use UP and DOWN to set SpO₂, and press "Start" to begin the test(the prompt"Timing!"is displayed in the interface), synchronously observe the device tested(as oximeter). When the value on it reaches the preset value, press "Stop", synchronously the time from Start to Stop will be displayed in the interface(unit:s).

2) Rate Alarm

Press UP and DOWN to move the prompt symbol to "Rate Alarm", press OK to enter the interface as follows:

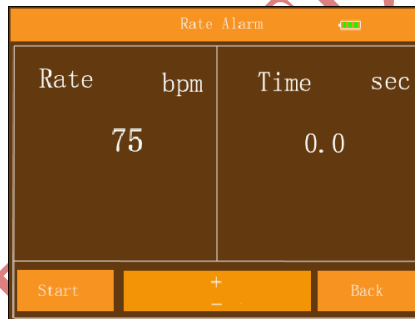


Figure 5-12 Rate Alarm

Use UP and DOWN to set Rate, and press "Start" to begin the test(the prompt"Timing!"is displayed in the interface), synchronously observe the device tested(as oximeter). When the value on it reaches the preset value, press "Stop", synchronously the time from Start to Stop will be displayed in the interface(unit:s).

3) Asystole

Press UP and DOWN to move the prompt symbol to "Asystole", press OK to enter the interface as follows:



Figure 5-13 Asystole Alarm

Press "Start" to begin the test(the prompt"Timing!"is displayed in the interface), synchronously observe the device tested(as oximeter). When the value on it reaches the preset value, press "Stop", synchronously the time from Start to Stop will be displayed in the interface(unit:s).

⚠ When "Start" is pressed, the inside calculagraph will clear automatically.

5.3.3 Amplitude

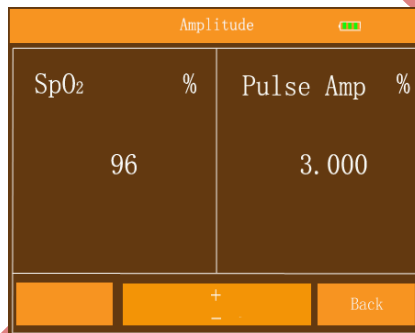


Figure 5-14 Amplitude

The information in this interface includes:

- 1) Current SpO₂
- 2) Current Pulse Amp

This device can simulate the SpO₂ and Rate in different Amplitude. Press UP and DOWN to set different Amplitude values to test. Press Back to return the superior menu. No operation for OK.

5.3.4 Preset

The screenshot shows a 'Preset' screen with an orange header. Below the header, it displays 'Condition: Normal'. The screen is divided into two columns: the left column shows 'SpO2 %' with a value of '96', and the right column shows 'Rate bpm' with a value of '75'. At the bottom, there is a navigation bar with a left arrow, a central up/down arrow, and a 'Back' button.

Figure 5-15 Preset

The information in this interface includes:

- 1) Current condition
- 2) SpO₂ in the current condition
- 3) Rate in the current condition

Preset 24 groups of SpO₂ and Rate values in different states, which is used for stimulating patient condition in different states simply. The default is 8 groups of data, and data groups can be change by setting "Motion level"(refer to 5.3.5). Press UP and DOWN to set different conditions to test.

24 conditions are listed as below:

Level 0 Preset			
No.	State	SpO ₂ (%)	Rate(bpm)
00	Normal	98	55
01	Weak Pulse	90	95
02	Bradycardia	88	45
03	Hypoxic	70	95
04	Neonate	90	180
05	Tachycardia	85	130
06	Geriatric	92	95
07	Obese	93	90
Level 1 Preset			
08	Normal/Tap	98	55
09	Normal/Shiver	98	55
10	Weak Pulse/Tap	90	95
11	Weak Shiver	90	95
12	Brad/Shiver	88	45
13	Hypoxic/Tap	70	95
14	Hypoxic/Shiver	70	95
15	Neonate/Shiver	90	180

Level 2 Preset			
16	Brady Tap #2	88	45
17	Hypox Tap #2	70	95
18	Weak Tap #2	80	95
19	Normal Tap #2	93	55
20	Asystole	91	90
21	Low Freq1	80	75
22	Low Freq2	70	75
23	Slow Tap	80	75

⚠ The 24 conditions above are not applicable to all oximeters.

5.3.5 Setting



Figure 5-16 Setting

The information in this interface is as follows:

- 1) Signal source
- 2) Step size
- 3) Motion level
- 4) Brightness
- 5) Key volume
- 6) Language Set

Press UP and DOWN to set the position of the prompt symbol, press OK to confirm the current selection. Press Back to return to the superior menu. No operation for LEFT and RIGHT in this interface.

a) Signal source setup

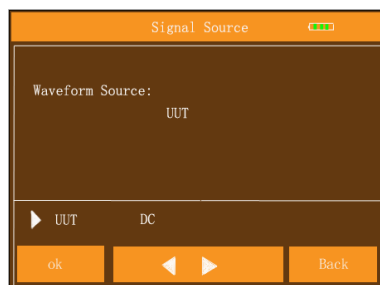


Figure 5-17 Signal Source

Move the prompt symbol to "UUT" and press OK to select UUT as **signal source**. Move the prompt symbol to "DC" and press OK to select DC as **signal source**.

b) Step size setup



Figure 5-18 Step Size

The **setting items in this interface are:**

- 1) SpO₂ step (1~10), resolution is 1.
- 2) Rate step (5~50), resolution is 5.

Press LEFT and RIGHT to select the adjusting item, and press UP and DOWN to increase and decrease the value. Press Back to return to the superior menu. No operation for OK.

c) Motion level



Figure 5-19 Motion level

The numbers of the selectable condition for different **motion levels** are different. Press UP and DOWN to adjust the **motion level**. Press Back to return to the superior menu. No operation for OK, LEFT and RIGHT.

d) Brightness



Figure 5-20 Brightness

Press UP and DOWN to adjust the brightness level. There are 3 selectable levels. Press Back to return to the superior menu. No operation for OK, LEFT and RIGHT.

e) Key volume



Figure 5-21 Key Volume

Press UP and DOWN to set the **key volume on or off**. Press Back to return to the superior menu. No operation for OK, LEFT and RIGHT.

f) Language Set



Figure 5-22 Language Set

Press UP and DOWN to set the **Language English or Chinese**. Press Back to return to the superior menu. No operation for OK, LEFT and RIGHT.

5.3.6 R-Curve



Figure 5-23 R-Curve

The compatible R-Curve preset currently:

BCI
Criticare
Datascopes
Datex
PMS M1190
Masimo
Nellcor
Nihon-Kohden
Ohmeda & Nova
Respironics

Press UP and DOWN to select the wanted R-curve. Press Back to return to the superior menu. No operation for OK, LEFT and RIGHT.

⚠ Some oximeters utilize technology or probes from other manufacturers. The R-Curve selected must correspond to the technology used to ensure accurate result. Please consult oximeter manufacturer for the correct technology and corresponding R-Curve.

Chapter 6 Maintain, Transportation and Storage

6.1 Maintain

- 1) Recharge the battery soon after the over-discharge. The device should be recharged once a month when it is not used for long. It can extend the battery life following this guidance.
- 2) The device needs to be calibrated once a year.

6.2 Transportation and Storage






- 1) The packed device can be transported by ordinary conveyance or according to transport contract. The device can not be transported mixed with toxic, harmful, corrosive material.
- 2) The packed device should be stored in room with no corrosive gases and good ventilation. Temperature: -20°C~+65°C; Relative Humidity: no more than 90%.

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Chapter 7 Troubleshooting

Trouble	Possible Reason	Solution
Prompt "NO RED LED NO IRED LED".	The unit under testing is placed improperly.	Please place the unit under testing properly.
Can't power on.	1) Low power or no power in battery. 2) Device damage.	1) Charge battery. 2) Contact with the local service center.
The display disappears suddenly.	1) Device damage. 2) Lower power in battery.	1) Charge battery. 2) Contact with the local service center.
Too short time for use after charge.	1) The battery is not charged full. 2) Battery damage.	1) Charge battery. 2) Contact with the local service center.
The battery is not charged full for more than 12 hours.	Battery damage.	Contact with the local service center.

Chapter 8 Key of Symbols

Signal	Description
	Warning – See User Manual
SpO ₂	Oxygen saturation(%)
Rate	Pulse rate(bpm)
TLC	Transfer Level Control
	Charge full
	Charge lack
Amp	Amplitude
UUT	Unit under test
DC	Direct component
	DC 5V
	The socket for adaptor

Chapter 9 Function Specification

SpO ₂ Parameter Specification	
Range	35%~100%
Resolution	1%
Accuracy	When SpO ₂ is 75%~100%, the error is $\pm 2\%$ or the device's accuracy, whichever is greater; when SpO ₂ is 50%~74%, the error is $\pm 3\%$ or the device's accuracy, whichever is greater; no definition when SpO ₂ is less than 50%.
Pulse Parameter Specification	
Range	25bpm~250bpm
Resolution	5bpm
Accuracy	$2\% \pm 2\text{bpm}$
Amplitude Parameter Specification	
Range	0.000%~20.000%
Resolution	1% for 1.000%~20.000%; 0.1% for 0.100%~0.900%; 0.025% for 0.000%~0.075%.
Battery Requirement	
Voltage 3.7 rechargeable lithium battery	
Battery working life	
Charge and discharge no less than 500 times	
Power Adapter	
Input Voltage	100 to 240 VAC, 50/60 Hz
Output voltage	5 VDC
Output current	3.0A
Output power	15 W
Dimensions and Weight	
Dimensions	190(L) × 125(W) × 59 (H) mm
Weight	450 Gram

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PATIENT SIMULATOR MED-S100

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